

REMARKS

Claims 14 and 15 are currently pending in the application. Claims 1-13 and 16-32 are herein canceled without prejudice. Claims 14 and 15 are in independent form and have been amended without prejudice.

Applicant wishes to express his appreciation for the courtesies extended Applicant's representative, Kenneth I. Kohn, during a telephonic interview conducted on May 4, 2009. During the telephonic interview, proposed amendments to the claims were discussed to continue examination on claims 14 and 15 and it was suggested by the Examiner to file a Request for Continued Examination, including the proposed amendments.

The application is objected to as failing to comply with the requirements of the sequence rules in that a sequence listing has not been filed. In response thereto, Applicants have included the sequence listing. The sequence identifiers have already been inserted in the specification in the amendment of July 15, 2008. Reconsideration of the objection is respectfully requested.

Claims 1-11 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for eliciting an immune response to exogenous tumor antigen, does not reasonably provide enablement for a method of immunotherapy to treat cancer comprising administering an effective amount of NCM without exogenous tumor antigen. Claims 1-11 have been canceled, rendering this rejection moot.

Claims 1-11 and 14-16 stand rejected under 35 U.S.C. § 102(b), as being anticipated by Meneses, et al. Specifically, the Office Action holds that Meneses, et al.

teaches a method of treating head and neck squamous cell carcinoma (H&NSCC) comprising administering an NCM comprising IL-1, IL-2, IL-6, IL-8, IL-10, IL-12, TNF- α , CSF, IFN- γ , and effective amounts of CY and INDO, in which 150 units of IL-2 equivalence by ELISA is administered. The Office Action further holds that it is noted that although the prior art does not explicitly teach "a synergistic anti-cancer treatment" or "a method of eliciting an immune response to tumor antigens" *per se*, given the same or nearly the same method step of administering an NCM plus CY and INDO for treating H&NSCC, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. The Office Action further holds that the presence of immature dendritic cells would be an inherent characterization of administering NCM to the patients in the prior art. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Meneses, et al., as applied to the claims, is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

With respect to canceled claims 1-11 and 16, the rejection is rendered moot. With respect to independent claims 14 and 15, Applicants have amended the claims to have closed language with respect to the cytokines. Meneses, et al. does not disclose administering CY and INDO with only the specific cytokines required in these claims.

Therefore, since Meneses, et al. does not disclose administering CY and INDO with the specific cytokines as set forth in the presently pending independent claims, the claims are patentable over Meneses, et al. and reconsideration of the rejection is respectfully requested.

Claims 1-11, 24, 26 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Meneses, et al. in view of Weiner, et al. Specifically, the Office Action holds that Meneses, et al. teaches as described above. Meneses, et al. does not teach further administering a tumor antigen. However, the Office Action holds that would have been obvious to one skilled in the art to administer an exogenous tumor antigen as part of anti-cancer immunotherapy as this was well known in the art at the time of the invention as evidenced by Weiner, et al. The Office Action holds that Weiner, et al. teaches administering tumor specific antigens along with immune adjuvants to activate immune cells such as dendritic cells in the immunization against tumor growth. In response thereto, claims 1-11, 24, 26, and 28 have been canceled, rendering this rejection moot.

Claims 1-2, 10-16, and 24-29 of this application have further been rejected as unpatentable based on non-statutory obviousness-type double patenting over Patent No. 6,977,072. As noted in the Office Action, these rejections can be readily overcome by the filing of a terminal disclaimer in compliance with 37 C.F.R. 1.321(c) or (d). Applicant stands ready to provide the appropriate terminal disclaimer upon the indication of the allowance of the pending claims.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as

discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In conclusion, it is respectfully submitted that the presently pending claims are in condition for allowance, which allowance is respectfully requested. Applicant respectfully requests to be contacted by telephone (248-539-5050) if any remaining issues exist.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

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CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB

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I hereby certify that this correspondence is being electronically filed with the United States Patent & trademark Office on the above date.

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